



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,320	02/07/2002	Russell Mumper	434-400 DIV	5127
1009	7590	07/05/2011		
KING & SCHICKLI, PLLC 247 NORTH BROADWAY LEXINGTON, KY 40507			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			07/05/2011	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/072,320  
Filing Date: February 07, 2002  
Appellant(s): MUMPER ET AL.

Patrick M. Torre, 55,684  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 05/16/2011 appealing from the Office action mailed 01/14/2011.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

An appeal brief was previously filed for this same application on 6/20/2005 appealing the final rejection filed 11/17/2004 by a different examiner. The board reversed the examiner on all counts. The prior art rejections cited in the final rejection filed 01/14/2011 and restated below are not the same as in the final rejection filed 6/20/2005.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 33,34,42-57 and 63-68 are pending in the application.

Claims 47-50 and 52-55 are withdrawn.

Claims 33,34,42-46,51,56,57 and 63-68 are rejected.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

6,270,783 B1	Slavtcheff et al.	8-2001
4,715,369	Suzuki et al.	12-1987
6,562,363 B1	Mantelle et al.	5-2003
5,877,131	Barnes	3-1999
6,265,346 B1	Reeves et al.	7-2001

Guo "Carbopol® Polymers for Pharmaceutical Drug Delivery Applications", Drug Delivery Technology, Vol. 3 No. 6 September 2003.

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

**Claims 33-34,42-46,56-57,65 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slavtcheff et al (US 6,270,783 B1) in view of Suzuki et al. (US 4,715,369).**

Slavtcheff discloses adhesive cosmetic strips which include a backing layer and an adhesive composition, the adhesive composition included dry to touch adhesives that normally contained a fluid and a structuring agent such as Carbomer (defined in appellant's specification as water-insoluble swellable anionic mucoadhesive polymer) in addition to a polymer, the polymer could be selected from anionic film forming polymers which include methacrylic acid and acrylic or methacrylic acid. See abstract, claims, col 4 lin 61-col 5 lin 29 and col 6 lin 4-15. While Slavtcheff is silent on the ratio of the structuring polymer carbomer to polymer, such adjustments to the concentration of ingredients within this adhesive are no more than ordinary and routine optimization. One of ordinary skill in the art has good reason to optimize the concentrations of ingredients within an adhesive composition for cosmetic use in order to optimize the stickiness of the adhesive. For instance, one would optimize the stickiness so that the patch, bandage etc. provided the desired adhesion to skin without being so sticky as to cause skin irritation or injury from pulled hair for example.

Slavtcheff does not disclose the thickness of the cosmetic strip or the use of a wax backing layer.

These deficiencies, however, are taught by Suzuki. As described in the previous office action filed 12/23/2008, Suzuki discloses the advantages of using a thin layer for adhesive patches and the use of a beeswax backing layer. Suzuki disclosed that thin films advantageously alleviates the feeling of touchy discomfort and makes itself applicable to flexure.

Thus from the disclosure of Slavtcheff and Suzuki, appellant's claimed thin bi-layer wax film containing an adhesive containing anionic polymers and a wax backing layer would have been obvious since the two references are related to the same general field of adhesives for personal use. Further, one of ordinary skill in the art would have a high expectation of success in using the backing layer of Suzuki and substituting it for the backing layer of Slavtcheff. The reason to make such a modification to Slavtcheff would be that the thin backing layer of Suzuki in combination with the adhesive of Slavtcheff would provide a thin adhesive strip which would advantageously alleviate the feeling of touchy discomfort and make itself applicable to flexure.

**Claims 33,34,42-46,51,56,57 and 63-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slavtcheff et al (US 6,270,783 B1) in view of Suzuki et al. (US 4,715,369) in view of Mantelle et al. (US 6,562,363 B1).**

Slatcheff and Suzuki are disclosed above as well as the reasoning for why their combination is obvious.

Neither Slatcheff or Suzuki describe the use of the specific mucoadhesive polymer polyacrylic acid crosslinked with polyalkenyl ether or divinyl glycol (Noveon) claimed in claims 66 and 68 or the specific film forming polymer Eudragit.

However, Mantelle, as discussed in the previous office action filed 05/01/2009, discloses the use of Noveon and Eudragit polymers in adhesive compositions for personal use.

Since all of the references above are related to the same general field of endeavor, it would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the polymers disclosed in Slatcheff and add the polymers disclosed within Mantelle. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of adhesives for personal use. It therefore follows that the instant claims define prime facie obvious subject matter.

**Claims 33-34,36-46,56-57 and 63-67 rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle et al. (US 6,562,363 B1) in view of Suzuki et al. (US 4,715,369).**

Mantelle discloses bioadhesive compositions for topical administration of an active agent that included polypeptides, antibacterials, anesthetics, analgesics and others to the skin or mucous membranes. See abstract, col 9 lin 44-col 13 lin 35 and claims. The bioadhesive contained a backing material. See col 3 lin 39-41. Suitable bioadhesives included Noveon polycarbophils and the bioadhesive could further comprise a pressure sensitive adhesive including acrylic adhesives such as Eudragit L100, same polymer as S100 exemplified in appellant's specification as an anionic film-forming polymer. See col 6 16-24, col 36 lin 66-col 38 lin 6 and example 2, particularly composition 42. Mantelle is silent on the ratio of the bioadhesive polymer carbomer to pressure sensitive adhesive Eudragit; however, such adjustments to the concentration of ingredients within this adhesive are no more than ordinary and routine optimization. One of ordinary skill in the art has good reason to optimize the concentrations of ingredients within an adhesive composition for active agent deliver to the skin or mucosal surface to optimize the stickiness of the adhesive. For instance, one would optimize the stickiness so that the patch, bandage etc. provided the desired adhesion to skin or mucosa surface without being so sticky as to cause irritation or injury.

Mantelle does not disclose the thickness of the cosmetic strip or the use of a wax backing layer.

These deficiencies, however, are taught by Suzuki as described in the previous office action mailed 12/23/2008. Suzuki discloses the advantages of using a thin layer for adhesive patches and the use of a wax backing layer. Suzuki disclosed that thin



films advantageously alleviates the feeling of touchy discomfort and makes itself applicable to flexure.

Thus from the disclosure of Mantelle and Suzuki, appellant's claimed thin bi-layer wax film containing an adhesive containing anionic polymers and a wax backing layer would have been obvious since the two references are related to the same general field of endeavor, bioadhesives for treating injury. Further, one of ordinary skill in the art would have a high expectation of success in using the backing layer of Suzuki and substituting it for the backing layer of Mantelle. The reason to make such a modification to Mantelle would be that the thin backing layer of Suzuki would provide a thin adhesive strip which would advantageously alleviate the feeling of touchy discomfort and make itself applicable to flexure.

#### **(10) Response to Argument**

##### **Response to section B of Appellant's Arguments, regarding combination of Slavtcheff and Suzuki.**

Appellants argue that the examiner has not provided a reasoning for picking the ingredients of Slavtcheff that read on the claimed pH-sensitive anionic mucoadhesive for delivering a molecule of interest to mucosal area.

In response to appellant's argument that the references do not describe a pH-sensitive anionic mucoadhesive for delivering a molecule of interest to mucosal area, the fact that the appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60

(Bd. Pat. App. & Inter. 1985). Slavtcheff clearly teaches an adhesive composition containing anionic film forming polymers and Carbomer structuring agents. Carbomer was previously claimed (original claim 37) as a water-insoluble swellable anionic mucoadhesive polymer, thus Slavtcheff discloses the use of both ingredients of appellant's claimed pH sensitive mucoadhesive layer. "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed"... *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). Since the ingredients are the same they will have the same properties and effects when used in the same way, in this instance, as an adhesive. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure or composition as that which is claimed, the properties appellant discloses and/or claims are necessarily present. See *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). MPEP 2112.01 [R-3] II.

Appellants further argue that there is not clear reasoning to combine the references.

The examiner does not find this argument persuasive. Clearly as noted in the rejection above, Slavtcheff teaches the same mucoadhesive layer and Suzuki teaches the same backing layer and the advantage of a thin adhesive. As previously noted in past office actions, the thin backing layer of Suzuki in combination with the adhesive of Slavtcheff would provide a thin adhesive strip which would advantageously alleviate the feeling of touchy discomfort and make itself applicable to flexure.

Appellants further argue that the claim recitation that the wax is bonded to the pH sensitive layer means, from the description in the specification, that “bonding” allows the claimed molecule of interest to be contained in and delivered from either the pH-sensitive anionic layer or the pharmaceutical wax layer. Appellants assert Suzuki fails to teach this feature.

This argument is confusing. The examiner must note that the independent claims do not require the active to be present in the backing layer. In response to appellant's argument that the references fail to show certain features of appellant's invention, it is noted that the features upon which appellant relies (i.e., backing layer can contain a molecule of interest) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, even though dependent claim 46 recites that the molecule of interest is contained in and released from either the pH-sensitive mucoadhesive layer or the water-insoluble layer, this claim is clearly written in the alternative format and does not preclude the presence of the molecule of interest in only the mucoadhesive layer.

Appellants further argue that since the examiner said in a 112 2nd rejection in the previous office action that a trademark name cannot be used to identify any particular product, he presumably cannot use a commercial name for a teaching of a specific product in a prior art rejection.

While appellant's reasoning is interesting, the examiner does not find it persuasive. The rejection was in regards to the claim set not to a description of a

particular material by its commercial product name in the prior art, in this case a copolymer. In the description of Slavtcheff, it clearly states the use of structuring agent Carbomer. In appellant's specification, this commercial product is identified as a water insoluble swellable anionic mucoadhesive polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol. See page 6 2nd paragraph. Furthermore in rebuttal, the examiner relies upon the teaching of Guo ("Carbopol® Polymers for Pharmaceutical Drug Delivery Applications", Drug Delivery Technology, Vol. 3 No. 6 September 2003), which clearly states that Carbopol polymers are polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol.

In regards to the combination of Slavtcheff and Suzuki, Section 3, appellants further argue that the primary function of Slavtcheff is a thermochromatic layer that provides a visual tool to the user, this feature would purportedly be blocked by the wax backing of Suzuki.

The examiner notes that the adhesive cosmetic strip of Slavtcheff uses a water insoluble flexible substrate with the adhesive dispersed or impregnated unto the substrate. The substrate material included natural and synthetic materials, which are not translucent, such as cotton, wood pulp and synthetic fibers. Even though these materials are not translucent, they do not prevent the invention of Slavcheff from providing the visual tool to the user provided by the thermochromatic layer. Besides the above, in rebuttal, the examiner relies on the disclosure of Barnes (US 5,877,131 A1, see claim 2) and Reeves et al. (US 6,265,346 B1, see col 3 lines 8-10) that beeswax, the material used as a backing layer in Suzuki, is translucent. Therefore based on this

evidence the examiner does not believe the thermochromatic layer would be blocked by beeswax in such a way that it would not perform its intended use.

In regards to dependent to the rejection of claims 34,42-46,57 and 65 over the combination of Slavtcheff and Suzuki, appellants believe the examiner has not identified the teaching or suggestion from the prior art that meets the limitations in these claims.

In regards to the amounts of mucoadhesive layer (claim 34), amount of polymer (claim 44) and the ratio of mucoadhesive polymer to anionic pH film forming copolymer (claim 65), the examiner noted in the rejection above that adjusting the amounts of these ingredients a result effective parameter which is obvious to adjust.

In regards to the melting point of the wax (claim 42 and 65), Suzuki teaches the use of the same wax described in appellants specification as a suitable wax with the requisite properties, beeswax. See page 7 last two paragraphs from appellant's specification. The same material will have the same properties.

As noted in the combination of Slavtcheff and Suzuki, the secondary reference Suzuki was already previously discussed in a previous office action filed 12/23/2008. The limitations of claims 42 and 44 were addressed in this action; Suzuki teaches a mixture of beeswax and PEG, the amounts of claim 44 were considered to be simple optimization of parameters.

In regards to clams 46, this claim does not preclude that the molecule of interest is released from just from the adhesive layer as described in Slavtcheff.

**Response to section C of Appellant's Arguments, regarding combination of Slavtcheff/Suzuki and Mantelle.**

Appellants argue that Mantelle's lengthy disclosure of the tradenames Noveon and Eudragit are applied to a number of different polymers with different properties and therefore cannot be used by the examiner for teaching a specific polymer.

The response to appellant's argument above on the use of tradenames in Slavtcheff is incorporated here. With regards to Eudraget polymers, Mantelle does not just describe the broad genus of Eudragit type polymers but describes specific species within the genus including Eudragit L100. As noted in the previous office action mailed 08/16/2010, Eudragit L100 is the same polymer as appellant's most preferred and exemplified anionic pH sensitive polymer, Eudragit S100. Noveon is described throughout appellant's specification and examples as a water insoluble swellable anionic mucoadhesive polymer of polyacrylic acid crosslinked with polyalkenyl ether or divinyl glycol. See page 6 2nd paragraph and examples from appellant's specification. From this definition, the examiner fairly assumes that Noveon is within the scope of the claimed water insoluble swellable anionic mucoadhesive polymer since it is described as such in appellant's specification.

Appellants argue that Mantelle expressly leads on of ordinary skill in the art to use PVP.

The secondary reference Mantelle was used primarily for its disclosure within that Eudragit S100 and Noveon were well known ingredients in adhesive technology. Simply because PVP is described in the adhesive of Mantelle does not mean that it must be added to the adhesive composition of the primary reference Slavtcheff, because one of ordinary skill in the art could add any of the disclosed adhesive

compounds of Mantelle to the adhesive of Slavtcheff. In addition, even if one of ordinary skill in the art added the PVP taught in Mantelle to an adhesive composition, it would not be precluded from independent claims 33,66 and 67. Appellants claim an adhesive; Mantelle teaches an adhesive containing PVP. Clearly PVP would not materially affect the basic and novel characteristic(s) of the claimed invention drawn to an adhesive since Mantelle uses this ingredient and the composition functions as an adhesive.

**Response to section D of Appellant's Arguments, combination of Mantelle and Suzuki.**

Appellants argue as above that there is no reason for the skilled artisan to contemplate the claimed combination of a pH sensitive mucoadhesive layer comprising water-insoluble swellable anionic mucoadhesive polymer and an anionic pH sensitive film forming copolymer, wherein the mucoadhesive layer is bonded to a pharmaceutical wax.

This argument is not found persuasive. Clearly Mantelle teaches bioadhesives for application to skin or mucous membranes, the bioadhesives featured a backing material. The bioadhesive included Noveon polycarbophils, defined in appellant's specification as water insoluble swellable anionic mucoadhesive polymer. The bioadhesive of Mantelle further comprised pressure sensitive adhesives including Eudragit L100, also known as S100, appellant's most preferred anionic pH sensitive film-forming copolymer as noted throughout the specification. Thus Mantelle clearly teaches the same mucoadhesive layer claimed, including the same 1) anionic mucoadhesive polymer and 2) anionic film forming copolymer. The ingredients are the

same, therefore any property claimed will be met since the same composition will have the same properties including the pH sensitivity and water solubility/swellability.

"Products of identical chemical composition cannot have mutually exclusive properties."

A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties appellant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). MPEP 2112.01 [R-3] II. Suzuki teaches the same backing layer and the advantage of a thin adhesive. As previously noted in past office actions, the thin backing layer of Suzuki in combination with the adhesive of Mantelle would provide a thin adhesive strip which would advantageously alleviate the feeling of touchy discomfort and make itself applicable to flexure.

Appellants argue that Mantelle's lengthy disclosure of the tradenames Noveon and Eudragit are applied to a number of different polymers with different properties and therefore cannot be used by the examiner for teaching a specific polymer.

With regard to Eudraget polymers, Mantelle does not just describe the broad genus of Eudragit type polymers but describes specific species within the genus including Eudragit L100, as noted in the previous office action mailed 08/16/2010. Eudragit L100 is the same polymer as appellant's most preferred and exemplified anionic pH sensitive polymer, Eudragit S100 (L100 and S100 are the same polymer). Noveon is described throughout appellant's specification and examples as a water insoluble swellable anionic mucoadhesive polymer of polyacrylic acid crosslinked with polyalkenyl ether or divinyl glycol. See page 6, 2nd paragraph and examples from



appellant's specification. From this definition, the examiner fairly assumes that Noveon is within the scope of the claimed water insoluble swellable anionic mucoadhesive polymer since it is described as such in appellant's specification.

Appellants argue Suzuki does not teach the element of delivering a molecule of interest from either the bioadhesive layer or wax layer.

The relevance of this assertion is unclear. Suzuki was a secondary reference used for its description of wax backing layers and the advantage of a thin adhesive for topical use. The primary reference, Mantelle, as noted above, teaches inclusion of a bioactive agent (a molecule of interest) in the adhesive layer. In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Appellants argue that Mantelle expressly leads on of ordinary skill in the art to use PVP.

PVP taught in Mantelle is not precluded from independent claims 33, 66 and 67. Appellants claim an adhesive; Mantelle teaches an adhesive containing PVP. Clearly PVP would not materially affect the basic and novel characteristic(s) of the claimed invention drawn to an adhesive since Mantelle uses this ingredient and the composition functions as an adhesive.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/James W Rogers/

Examiner, Art Unit 1618

Conferees:

/MICHAEL G. HARTLEY/

Supervisory Patent Examiner, Art Unit 1618

/KATHLEEN K BRAGDON/

Primary Examiner, Art Unit 1600